

## Relugolix (ORGOVYX) Criteria for Use March 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRANet](#) site for further information.

### Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive relugolix.

- ☐ Care not provided by a VA or VA Community Care provider of urology or hematology/oncology services
- ☐ Unmanageable drug interaction identified
- ☐ End stage renal disease (with or without hemodialysis)
- ☐ Child-Pugh class C
- ☐ QTc > 470 msec, Q-wave infarction or congenital long QT syndrome
- ☐ Uncontrolled or symptomatic ventricular arrhythmias in the prior 6 months
- ☐ Congestive heart failure (NYHA Class 3 or 4) in the prior 6 months
- ☐ A thromboembolic event in the prior 6 months
- ☐ Gastrointestinal condition that may interfere with relugolix absorption
- ☐ Unable to swallow oral tablets whole and intact
- ☐ Known history of non-adherence with oral medication, follow-up appointments or laboratory visits

### Inclusion Criteria

At least one of the following must be fulfilled in order to meet criteria:

- ☐ Inability to maintain castrate levels of serum testosterone on LHRH agonist therapy (taking into consideration the initial time required to reach castrate level)
- ☐ Known hypersensitivity to LHRH agonist analogs or their components
- ☐ Rapid decrease in testosterone levels needed due to organ-threatening disease

### Additional Inclusion Criteria

All of the following must be fulfilled in order to meet criteria:

- ☐ Hormone-sensitive, advanced adenocarcinoma of the prostate
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented.
- ☐ Advise male patients with female partners of childbearing potential to use effective contraception during and for 2 weeks following the last dose of relugolix